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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/821,662

Applicant(s)

JOLLY ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-37 is/are pending in the application.
- 4a) Of the above claim(s) 31-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application filed March 29, 2001, is a continuation of 08/978,293 filed November 25, 1997 now abandoned; and is a continuation in part of 08/155,944, filed January 19, 1996, now abandoned, which is a continuation in part of 08/122,791 filed September 15, 1993, now abandoned, which is a continuation in part of 07/965,084 filed October 22, 1993, now abandoned, which is a continuation in part of 07/586,603 filed September 21, 1990, now abandoned, which is a continuation in part of 07/565,606 filed October 11, 1990, now abandoned, which is a continuation in part of 07/395,932 filed March 21, 1988, which is a continuation in part of 07/170,515; and is a continuation in part of 08/102,132, which is a continuation in part of 08/032,385, which is a continuation in part of 07/830,417, filed February 4, 1992, now abandoned; and is a continuation in part of 08/104,424, filed August 9, 1993, now abandoned, which is a continuation of 07/800,328 filed August 9, 1993, now abandoned.

Claims 22-37 are pending and currently under examination.

Election/Restrictions

Applicant's election of Group 1, claims 22-30, in the reply filed on June 7, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

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Claims 22-37 are pending. Claims 31-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 22-30, drawn to a method of inhibiting a solid tumor growth *in vivo* comprising administering two or more retroviral vectors each expressing different cytokine molecules, wherein expression results in inhibition of tumor growth, are currently under examination.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

It is noted that the present claims find full support in application 08/978,293, filed November 25, 1997. However, while the claim for priority to CIP applications 08/155,944, 08/102,132 and 08/104,424 is noted, a review of the disclosures indicate that they do not fully support the instantly claimed invention. Therefore, the priority given the instant application is that of November 25, 1997.

Specification

The disclosure is objected to because of the following informalities: it is noted that the specification makes reference at multiple locations to US applications, however the specific application number was not inserted. See for example page 45, line 20, page 53, lines 25 and 28.

Review of the entire specification for appropriate correction is required.

In addition, it is noted that a sequence listing has been filed and entered, however upon review of the disclosure it is noted that Figure 4 contains a sequence listing that has not been identified by SEQ ID NO neither in the drawing nor the description of the drawing. The nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825.

Appropriate correction is required.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

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subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Culver *et al.*

Culver *et al.* state that 'the object of the present invention [is] to provide a method of using retroviral vector gene-transfer *in situ*' (page 4; line 13). More specifically, Culver *et al.* teach a method of inhibiting tumor growth comprising administering a retroviral vector encoding a prodrug converting enzyme, such as HSVTK, in combination with an immune enhancing cytokine (see entire patent, especially pages 3 and 5). In a preferred embodiment, Culver *et al.* teach that 'a second nucleotide sequence coding for an immune response-enhancing substance' can be used (page 4; lines 32-37). Culver *et al.* also teach that introduction of the cytokine can be introduced into the targeted tumor via the same vector or via a mixture of the different producer cell lines (page 16; lines 12-17). Further, the claims of the invention recite and teach the use of a retroviral vector (page 25; claims 1-3). Culver *et al.* teach the use of different promoters to control the expression of genes, in particular to control the unduly toxic effects of a cytokine in treating a brain tumor. Culver *et al.* provide the necessary teaching and guidance that anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Culver *et al.* (US Patent 6,045,789) and Rosenthal *et al.*

Culver *et al.* state that 'the object of the present invention [is] to provide a method of using retroviral vector gene-transfer *in situ*' (page 4; line 13). More specifically, Culver *et al.* teach a method of inhibiting tumor growth comprising administering a retroviral vector encoding a prodrug converting enzyme, such as HSVTK, in combination with an immune enhancing cytokine (see entire patent, especially pages 3 and 5). In a preferred embodiment, Culver *et al.* teach that 'a second nucleotide sequence coding for an immune response-enhancing substance' can be used (page 4; lines 32-37). Culver *et al.* also teach that introduction of the cytokine can be introduced into the targeted tumor via the same vector or via a mixture of the different producer cell lines (page 16; lines 12-17). Further, the claims of the invention recite and teach the use of a retroviral vector (page 25; claims 1-3). Culver *et al.* teach the use of different promoters to control the expression of genes, in particular to control the unduly toxic effects of a cytokine in treating a brain tumor. Rosenthal teach a method directed to *ex vivo* gene therapy using a combination of IL-2 with GM-CSF or γ -interferon. It is noted that the introduction of the retrovirus as taught by Rosenthal was done *ex vivo*, however, it is clear that it is the expression of the genes *in vivo* that result in the decrease tumor size (page 1295; figure 7 and summary page 1296; final paragraph). It would have been obvious for one of ordinary skill in the art, at the time the invention was made, to use multiple gene delivery vehicles to express different cytokine molecules to inhibit the growth of a tumor *in vivo*. One having ordinary skill in the art would

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have been motivated to combine and use the beneficial findings of Rosenthal *et al.* for the treatment of tumors with that of Culver *et al.* to provide an effective treatment for killing tumor cells and reducing tumor size *in vivo* as suggested by Culver *et al.* There would have been a reasonable expectation of success given the results of both Culver *et al.* and Rosenthal *et al.* demonstrating the ability of the HSVTK and cytokines to effectively affect tumor cells *in vitro* and *in vivo*.

Thus, it would have been obvious for one of ordinary skill in the art, at the time the invention was made, to use multiple gene delivery vehicles to express a combination of IL-2 with GM-CSF or γ -interferon to inhibit the growth of a tumor *in vivo*.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

Joe Woitach
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